

WHAT IS CLAIMED IS:

1. A nucleic acid segment comprising a synthetic promoter/enhancer, or the complement of such a promoter/enhancer wherein the promoter/enhancer is optimized for use in genetic immunization and/or gene therapy.
2. The nucleic segment of claim 1, wherein the promoter/enhancer comprises a promoter sequence comprising regions encoding promoter elements including a TATA box, a TFIIB binding element, an initiator, a downstream promoter element, and an upstream binding element.
3. The nucleic acid segment of claim 2, wherein the promoter sequence is further defined as comprising, as an upstream binding element, at least an IRF binding element.
4. The nucleic acid segment of claim 3, wherein the promoter sequence is further defined as comprising, as upstream binding elements, at least an SP1 binding element and an IRF binding element.
5. The nucleic acid segment of claim 2, wherein the promoter sequence is further defined as comprising, as upstream binding elements, at least an SP1 binding element, an α -interferon regulatory factor 1 (IRF 1) binding element, a CBP binding element, an NF κ B binding element, and an AP1 binding element.
6. The nucleic acid segment of claim 1, further defined as comprising an enhancer sequence comprising one or more additional binding elements selected from the group consisting of the SP1, IRF, CBP, AP1, C-Jun, NF κ B, CREB/ATF, and NF1 binding elements.

7. The nucleic acid segment of claim 2, further defined as comprising at least one spacer region between two or more regions encoding a promoter element and/or an enhancer element.
- 5 8. The nucleic acid segment of claim 7, wherein the spacer region has no protein binding activity.
9. The nucleic acid segment of claim 7, wherein the spacer region has an approximately equal distribution of adenine, guanine, cytosine, and thymine bases.
- 10 10. The nucleic acid segment of claim 7, wherein the spacer region comprises three consecutive adenine bases.
11. The nucleic acid segment of claim 7, wherein the spacer region comprises three consecutive thymine bases.
- 15 12. The nucleic acid segment of claim 2, wherein the promoter sequence is further defined as comprising the sequence of SEQ ID NO:35.
- 20 13. The nucleic acid segment of claim 12, further defined as comprising the sequence of SEQ ID NO:36.
14. The nucleic acid segment of claim 12, further defined as comprising the sequence of SEQ ID NO:37.
- 25 15. The nucleic acid segment of claim 1, further defined as comprising a nucleic acid segment encoding or potentially encoding an immunogenic peptide or polypeptide.
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16. The nucleic acid segment of claim 15, wherein the immunogenic polypeptide is HIV gp120.
- 5 17. The nucleic acid segment of claim 15, further defined as a linear or circular expression element.
18. The nucleic acid segment of claim 15, further defined as a vector.
- 10 19. The nucleic acid segment of claim 18, wherein the vector is further defined as a genetic immunization vector, viral vector, plasmid vector, phagemid, cosmid, BAC, YAC or MAC.
20. The nucleic acid segment of claim 15, further defined as being comprised in a pharmaceutical composition.
- 15 21. A nucleic acid segment comprising a promoter sequence comprising regions encoding promoter elements including a TATA box, a TFIIB binding element, an initiator, a downstream promoter element, and an upstream binding element.
- 20 22. A method of expressing a polypeptide in a subject comprising:
- 25 (a) obtaining a first nucleic acid segment comprising a region encoding a synthetic promoter/enhancer wherein the promoter/enhancer is optimized for use in genetic immunization and/or gene expression;
- (b) obtaining a second nucleic acid segment comprising a region encoding the polypeptide;
- (c) operatively linking the first nucleic acid to the second nucleic acid to form a construct comprising at least the region encoding the promoter and the region encoding the polypeptide; and
- (d) administering the construct to the subject.
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23. The method of claim 22, wherein the promoter/enhancer is further defined as comprising a promoter sequence comprising regions encoding promoter elements including a TATA box, a TFIIB binding element, an initiator, a downstream promoter element, and an upstream binding element.
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24. The method of claim 23, wherein the promoter sequence is further defined as comprising, as upstream binding elements, at least an SP1 binding element, an α -interferon regulatory factor 1 (IRF 1) binding element, a CBP binding element, an NF κ B binding element, and an AP1 binding element.
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25. The method of claim 22, further defined as comprising an enhancer sequence comprising one or more additional binding elements selected from the group consisting of the SP1, IRF, CBP, AP1, C-Jun, NF κ B, CREB/ATF, and NF1 binding elements.
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26. The method of claim 22, further defined as a method of genetic immunization.
27. The method of claim 26, wherein the subject is immunized against the peptide or polypeptide.
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28. The method of claim 22, further defined as a method of expression library immunization.
29. The method of claim 22, wherein the construct is further defined as a linear or
- 25 circular expression element.
30. The method of claim 22, wherein the construct is further defined as a vector.
31. The method of claim 30, wherein the vector is further defined as a genetic
- 30 immunization vector, viral vector, plasmid vector, phagemid, cosmid, BAC, YAC or MAC.

32. The method of claim 22, wherein the construct is further defined as being comprised in a pharmaceutical composition prior to administration to the subject.

5 33. The method of claim 22, wherein the subject is a mammal.

34. The method of claim 33, wherein the mammal is a human.

35. The method of claim 33, wherein the mammal is a mouse.

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